

### **REMARKS**

The present communication responds to the Office Action dated March 17, 2008. In that Action, the Examiner rejected claims 1, 26-31, 33 and 35 under 35 U.S.C. § 112 and rejected claims 1, 25-31 and 33 under 35 U.S.C. § 102(b). The Examiner also rejected claim 35 under 35 U.S.C. § 103(a). The rejections are traversed and reconsideration and allowance are requested at least for the following reasons.

#### **Claim Rejection Under 35 U.S.C. § 112**

Previous claims 1, 26-31, 33 and 35 were rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The Applicants traverse the rejection for at least the following reasons.

#### **Claims 1, 25-31, 35-37, 40-42 are Allowable under 35 U.S.C. § 112, first paragraph**

The Examiner rejected claims 1, 26-31, 33, and 35 as including subject matter not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors had possession of the claimed invention at the time the application was filed. Specifically, the Examiner asserted that the claim recitation of an underpad having a bottom surface that is impermeable to bodily fluids is not supported by the specification. The Applicants respectfully assert that such recitation is supported by the specification.

While there is no in haec verba requirement, newly added claim limitations must be supported in the specification through express, implicit, or inherent disclosure . . . The fundamental factual inquiry is whether the specification conveys with reasonable clarity to those skilled in the art that, as of the filing date sought, applicant was in possession of the invention as now claimed. *MPEP § 2163 (I)(b)*.

To expedite prosecution of the present application, claims 1 and 25 have been amended to recite, “at least one under pad/bed liner configured to be positioned on a surface, the under pad/bed liner having a bottom layer and a top layer, wherein the top layer is designed to absorb bodily fluids, and wherein the bottom layer protects the surface from bodily fluids that soak

through the top layer.” New claim 40, however, recites, “[t]he miscarriage kit of claim 1, wherein the bottom layer of the under pad/bed liner is impermeable to bodily fluids,” the limitation previously rejected by the Examiner. The Applicants respectfully assert that the specification supports “bottom layer protects ...” and “impermeable” either explicitly or implicitly.

The specification describes an underpad/bed liner with a “pad backing [which] is made from a thick polypropylene and has a non-skid feature to ensure the product stays in place. The bed-liner has an absorbent padding that is adhered to one side of the backing. This absorbent padding is centered onto the backing with a 1.5” frame surrounding the pad. In one embodiment, the disposable underpad/bed-liner is mint green with a white absorbent pad and is offered by First Quality Products, Inc. of McElhattan, PA.” *Current Specification, paragraph 50*. The specification goes on to state the purpose of the underpad/bed liner is “to assist in keeping the woman's surroundings sanitary by absorbing bodily fluids. For example, the underpad/bed-liners are useful where a woman chooses to miscarry in a bed, chair, sofa or other physical surroundings. The bed-liner helps to reduce worries about blood or fluid soaked bedding or fabrics and the discomfort of washing or cleaning these after miscarriage.” *Current Specification, paragraph 51*.

The Applicants first note that the specification supports the existence of an under pad/bed liner having a bottom surface and a top surface. Paragraph [0050] of the present specification reads “The bed-liner has an absorbent padding that is adhered to one side of the backing.” This explicitly states the dual layer nature of the underpad /bed-liner, with one layer that is both absorbent and padded and a further backing, or bottom, layer.

The claim language: “bottom layer protects the surface from bodily fluids that soak through the top layer” is supported at least by paragraph [0051] of the present specification which indicates that “[t]he bed-liner helps to reduce worries about blood or fluid soaked bedding or fabrics and the discomfort of washing or cleaning these after miscarriage.” *Current Specification, paragraph 51*. At least because a woman may choose to “miscarry in a bed, chair, sofa, or other physical surroundings,” *Current Specification, paragraph 51, lls. 7-8*, and a miscarriage often can take between several hours and several days, this would lead one skilled in

the art to reasonably understand that the under-pad/bed liner protects the surface upon which it is placed from the possibility of blood flow that soaks through the top absorbent layer. One reasonably skilled in the art would recognize that an underpad/bed liner would need to have both an absorbent top layer and a protective bottom layer in the event that the amount of blood and fluid expelled during the miscarriage exceeds the amount of blood that the top absorbent layer can handle.

New claim 40 contains an under pad/bed liner that has a bottom layer that is “impermeable to bodily fluids.” In the last office action, the Examiner argued that this language is not supported by the specification because “[p]olypropylene materials such as nonwoven fabrics are not inherently liquid impermeable, and are often permeable to liquids. Therefore, the claim limitation disclosing a liquid impermeable bottom surface is not supported by the specification as originally filed, and constitutes new matter.” *Current Office Action, page 4*. For purposes of support in the specification, polypropylene can be impermeable. While polypropylene may be impermeable or permeable depending on configuration, this spectrum of characteristics does not cause the disclosure of polypropylene to not support an impermeable layer – polypropylene may be impermeable and, in the context of the present specification, would be understood by one skilled in the art to be impermeable. This is at least because a fluid permeable backing would do no good towards fulfilling the objective of the underpad/bed liner in that it would not protect the surface on which it is placed from fluids that soak through the upper layer. Accordingly, the Applicants respectfully submit that one skilled in the art would interpret a polypropylene layer in the context described in the specification to be impermeable.

Finally, the specification discloses as a suitable bed-liner the Prevail ® brand under pads from First Quality Products, Inc. “The underpad/ bed liner has one embodiment that is “mint green with a white absorbent pad and is offered by First Quality Products, Inc. of McElhattan, Pa.” See *Current Specification, paragraph 50*. A product selection guide can be viewed at: <http://www.firstquality.com/default.aspx?pageid=121> . Attached as Appendix A The Prevail® brand under pads are the only underpad/bed liners that First Quality Products, Inc. sells that meet the other descriptions in the patent specification. First Quality Products describes this pad as “[f]or bed or chair protection.”

For at least the preceding reasons, the Applicants feel that the current specification fully supports the claims as amended that recite an underpad/bed liner that is “designed to absorb bodily fluids ... wherein the bottom layer protects the surface from bodily fluids that soak through the top layer,” *Claims 1, 25-31, 35-42*, and an underpad/bed liner that is “impermeable to liquids.” *Claim 40*. Withdrawal of the rejection under 35 U.S.C. 112, first paragraph, is thus respectfully requested.

**Claim Rejection Under 35 U.S.C. § 102(b)**

Claims 1, 25-31 and 33 were rejected under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as being obvious over, Schumacher (US 4,917,238).

*Claims 1, 25-31, 35, New Claims 36-42 Are Not Anticipated by Schumacher*

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *MPEP § 2137*.

Claims 1 and 35 recite, at least, “one under pad/bed liner” ... “configured to be positioned on a surface, the under pad/bed liner having a bottom layer and a top layer, wherein the top layer is designed to absorb bodily fluids, and wherein the bottom layer protects the surface from bodily fluids that soak through the top layer”, “one sanitary napkin”, “one towel”, “one pair of gloves”, “one specimen pan for receiving human tissue”, and “one container for holding fetal remains for legal disposition.”

In addition to the elements provided above in discussion of claims 1 and 35, claim 35 recites a “specimen pan, wherein the specimen pan is configured to fit inside the rim of a toilet ... comprised of a durable material; and wherein the specimen pan provides a measurement guide for measurement of fluid loss,” claim 38 recites a “thermometer,” and claim 39 recites a “protective undergarment.”

In contrast, Schumacher discloses “a kit for cleaning up human waste in a manner which abates risk of transfer of infectious diseases to the person cleaning the waste. Another object of the present invention is to provide such a cleanup kit which may be used for a single instance of waste cleanup and readily disposed.” *Schumacher col. 1, ll. 34-40*. Schumacher discloses “a main container”, “absorbent material”, “a disinfectant”, “a means for scooping up waste material”, “at least one glove”, “at least one absorbent towel”, “at least one germicidal handwipe”, “at least one plastic bag.” *See, e.g., Schumacher claim 1*.

As discussed more fully below, Schumacher does not disclose, teach, or suggest, “an underpad/bed liner” or “at least one specimen pan for receiving human tissue” as recited by claims 1, 25-31, 35-42, a “specimen pan, wherein the specimen pan is configured to fit inside the rim of a toilet .... comprised of a durable material; and wherein the specimen pan provides a measurement guide for measurement of fluid loss”, as recited by claim 35, or a thermometer, as recited by claim 38, or a protective undergarment as recited by claim 39. Therefore, under well established rules of anticipation, Schumacher does not anticipate the claims of the current application.

A. Schumacher does not disclose, teach, or suggest an underpad/bed liner

In her last Office Action, the Examiner refers to element 52 of Schumacher as comprising a “pad having an absorbent surface.” *Current Office Action page 5, line 6*. To support her position, the Examiner refers to Col. 2, ll. 45-47 of Schumacher. This portion of Schumacher is reproduced below:

The kit 10 includes a plurality of kit contents shown in Fig. 1. The kit contents include preferably three disposable towels 50,51,52 (preferably absorbent paper towels or the like). *Schumacher Col. 2, ll. 45-47*.

The only elements of Schumacher that the Examiner could be referring to are “[t]hree disposable towels (preferably absorbent paper towels or the like).” *Schumacher, col. 2, ll. 45-47*. Accordingly, element 52 of Schumacher comprises a disposable towels.

The Applicants respectfully submit that the paper towels of Schumacher cannot reasonably be used to anticipate an underpad bed liner “configured to be positioned on a

surface,” and “having a bottom layer and a top layer, wherein the top layer is designed to absorb bodily fluids and wherein the bottom layer protects the surface from bodily fluids that soak through the top layer,” as claimed.

“[T]he meaning of a prior art reference requires analysis of the understanding of an artisan of ordinary skill .... To anticipate, ‘[t]here must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of the invention.’” *Finisar Corp. v. DirecTV Group, Inc.*, 523 F.3d 1323 (Fed. Cir. 2008) (quoting *Scripps Clinic & Res. Found. v. Genentech, Inc.*, 927 F.2d 1565, 1576 (Fed. Cir. 1991)). Furthermore, “variations, scarcely noticeable to a common reader, would be detected by an expert in the art” *Bischoff v. Wethered*, 76 U.S. 812, 815, 19 L. Ed. 829 (1870). One reasonably skilled in the art would understand the difference between a disposable towel and an underpad / bedliner. The latter being for the containment of fluids over an extended period of time and the protection of surfaces, the former for the clean up of already expelled fluids that can be easily disposed of. Disposable towels do not generally contain the absorbency necessary to absorb the bodily fluids expelled during a miscarriage and at the same time protect the undersurface in the same way as a underpad/bed liner. The specification of Schumacher and of the present application bears this out in more detail, and the differences between the elements are clear when evaluated “in light of the [whole] specification.” (Claims are to be read in light of the specifications, *See MPEP § 2111*). Schumacher discloses an invention “to provide a kit for cleaning up human waste in a manner which abates risk of transfer of infectious diseases to the person cleaning the waste.” *Schumacher, col. 1, ll. 33-36*. This gives context and meaning to the absorbent disposable towel term in Schumacher as relating only to cleaning up of bodily fluids and having an absorbency relating only to the one time cleanup of said fluids. In contrast, the current disclosure describes the underpad/bedliners to “reduce worries about blood or fluid soaked bedding or fabrics and the discomfort of washing or cleaning these after a miscarriage.” *Current Specification, paragraph 51*.

1. The Examiner’s reading of the claims violates canons of claim construction.

The current claims call also for separate elements of a “towel,” as well as the “underpad/bed liner”. The Examiner’s argument that the towel in Schumacher is equivalent to

an underpad/bed liner in the current application ignores the separate, claimed element of a towel in the current application. More particularly, each of the independent claims recite, in addition to a bedliner, a “towel”. Equating a towel to mean underpad/bedliner violates the fundamental canon of claim differentiation in interpreting claims. Because there are two separate and distinct elements in the present claims – “towel” and “underpad/bed liners” – the elements must be distinct, and the Examiner’s current theory that “disposable towel” is the same as “underpad/bed liners,” is not a reasonable construction of the current application. “A claim construction that gives meaning to all the terms of the claim is preferred over one that does not do so.” *Merck & Co. v. Teva Pharms. USA, Inc.*, 395 F.3d 1364, 1372 (Fed. Cir. 2005).

**B. Schumacher Does Not Disclose, Teach, or Suggest a Specimen Pan.**

In her last Office Action, the Examiner asserts that the “specimen pan 80 [of Schumacher] is fully capable of receiving human tissue ...” *Current Office Action*, page 5. The item referred to as a specimen pan, element number 80, is, in fact, a “Scoop 80.” *Schumacher*, col. 3, l. 36. This scoop, as disclosed in Schumacher is a collapsible, disposable, preferably cardboard scoop used to collect solid bodily fluids (or fluids that have become solid as a result of using the “absorbent”). See *Schumacher*, col. 3, ll. 36-68; col. 4 ll. 1-6. “The scraper and scoop are necessary for preliminary cleanup.” *Schumacher*, col 4, ll. 55-57.

Claim 1 recites a “specimen pan for receiving human tissue.” Claim 35, as amended, recites a “specimen pan, wherein the specimen pan is configured to fit inside the rim of a toilet and further includes an upper rim configured to allow the upper rim to rest atop the toilet rim, the specimen pan having an opening positioned and sized to receive fluids and human tissue from a miscarriage, and wherein the specimen pan is comprised of a durable material; and wherein the specimen pan provides a measurement guide for measurement of fluid loss.” As discussed in the specification of the current application, the functions of the specimen pan include:

“assisting in collecting and/or calculating blood or other bodily fluid loss for recording purposes. Fluid loss may be monitored and recorded to determine whether safe limits have been exceeded. The specimen pan can also be used to collect tissue and/or fetal remains, sparing the additional trauma of retrieving fetal remains from an unsanitary toilet. Once the bodily fluids, tissue and/or fetal remains are collected in the pan, they may be transferred to a spill-proof, sanitary container ...” *Current Specification*, paragraph 54.

The scoop defined by Schumacher cannot properly be construed as a specimen pan, as claimed. The Schumacher scoop is defined such that one side is not enclosed so that bodily waste may be “scooped” into said scoop. *See Schumacher, Id.* In contrast, the claimed specimen does not (and could not) have such a gap. *See, for example, Current Specification, Figure 3A, 3B.* The specimen pan cannot have the gap necessarily present in the scoop of Schumacher and still fulfill its purpose of catching human tissue and fluid as it is expelled out the body, as discussed in the present application. Attempting to use the scoop 80 of Schumacher to do so would result in the bodily fluids and tissue leaking out the open end of the scoop. The Schumacher scoop and the current specimen pan are structurally distinct.

C. Schumacher Does Not Disclose, Teach, or Suggest a Container for Holding Fetal Remains for Legal Disposition.

In her last Office Action, the Examiner stated that “the container 64 [of Schumacher] is fully capable of holding fetal remains.” “Container 64” as the Examiner calls it, is a “plastic bottle and cap for containing a metered amount of chlorine solution.” *Schumacher, col. 3, ll. 1-19.* The bottle is specifically sized so that it holds 6-7 fluid ounces. *Schumacher, col. 3, ll. 15-16.*

The plastic bottle 64 of Schumacher is unusable for the present invention which requires at least 300 grams to hold fetal remains. *See Dean Affidavit, page 2* The affidavit under 37 CFR 1.132, filed 1/07/2008, set forth the average amount of fetal remains expelled during miscarriage and discussed that Schumacher would not be suitable for collecting such remains. In response, the Examiner conclusively dismisses the facts set forth in the affidavit as “not supported by any documentary evidence.” *Current Office Action, page 2.* The Applicants respectfully assert that the amount of fetal remains generally expelled during a miscarriage is a well-known medical fact, discussed more fully below, and not one likely to be disputed by any skilled in the art.

The Applicants respectfully submit that the plastic bottle for chlorine solution cannot properly be construed as a “container for holding fetal remains for legal disposition,” as recited by claims 1, 35, 38. The Examiner has provided no guidance as to how the bottle could hold fetal remains, nor how the fetal remains could be put into the bottle, given that the bottle neck is very narrow. *Schumacher Figure 1, element number 64.*

D. Conclusion for Claims 1, 25-31, 35-37, 40-42



Schumacher does not disclose an underpad/bed liner “configured to be positioned on a surface, the under pad/bed liner having a bottom layer and a top layer, wherein the top layer is designed to absorb bodily fluids, and wherein the bottom layer protects the surface from bodily fluids that soak through the top layer,” nor does Schumacher disclose a specimen pan or a container for holding fetal remains for legal disposition. Claims 1, 25-31, 35-37, 40-42 are thus allowable over Schumacher. Reconsideration and allowance are thus respectfully submitted.

E. New Claims 38 and 39 have additional elements not disclosed, taught, or suggested by Schumacher

New claims 36-37 are not anticipated for the added reasons that they include additional elements (“at least one thermometer” *Claim 38* and “at least one protective undergarment” *Claims 39*) not present in Schumacher and therefore Schumacher does not anticipate for failure to satisfy the “all elements rule.”

Schumacher does not disclose, in addition to elements discussed above, at least one thermometer or at least one protective undergarment as recited by claims 36 and 37. Claims 36 and 37 are thus allowable over Schumacher. Reconsideration and allowance are thus respectfully submitted.

**Claim Rejection Under 35 U.S.C. § 103 In Light Of Schumacher Only**

*Claims 1, 25-31, 33, New Claims 36-37 Are Not Obvious in Light of Schumacher*

**A. Office Action States Insufficient Grounds for Obviousness Rejection**

In framing her rejection of the claims over Schumacher, the Examiner rejects the claims under 102(b) as anticipated by Schumacher or, in the alternative, under 103(a) as obvious over Schumacher. The present office action does not detail the grounds to which the present application is obvious in light of only Schumacher, but simply makes a conclusory statement that in addition to being anticipated by Schumacher, the present application “in the alternative, under 35 U.S.C. 103(a) [is] obvious over Schumacher (4,917,238).” *Current Office Action, page 5*. The Applicants assume that the alternative obviousness rejection is to correct for the fundamental teaching deficiencies of the Schumacher reference for the anticipation rejection, detailed above.

However, the Applicants respectfully assert that the Examiner still must meet the standard under 35 U.S.C. § 103 that “the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious ... to a person having ordinary skill in the art ...” *Id. See also KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (U.S. 2007).

While the MPEP and numerous court decisions specifically direct examiners to provide clear reasons for rejection on obviousness grounds, the current office action does not specifically state the grounds for rejection on obviousness in light of *only* Schumacher. *See MPEP § 2141, KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (U.S. 2007) (“[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness”)(quoting *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006)). In the office action, the Examiner discusses Schumacher in terms of anticipation, and Schumacher in light of Gordon for obviousness, but not the give any explanation of the present claims being rejected as obvious over *only* Schumacher.

The Applicants opine that the Examiner may be relying on the previous office action’s argument regarding obviousness only in light of Schumacher, *Office Action of 9/11/2007, page 3-4*. The Applicants surmise this based on the fact that substantially the same text and arguments are used in the current office application as the basis for the novelty rejection. *See Current Office Action, page 4-5*. If this is the Examiner’s intent, the Applicants respectfully note that mixing novelty and obviousness analysis is discouraged by the courts. *See TorPharm Inc. v. Ranbaxy Pharms., Inc.*, 336 F.3d 1322, 1326 FN3 (Fed. Cir., 2003) (stating that while lack of novelty is the epitome of non-obviousness, “novelty and nonobviousness are separate concepts that are best kept analytically distinct”).

The Examiner’s analysis in the previous office action also fails to resolve the *Graham* inquiries as recommended by the MPEP, *see MPEP § 2141(II)* (“The question of obviousness must be resolved on the basis of [the *Graham*] factual determinations”). Furthermore, the Examiner’s arguments fail to state the grounds upon which rejection is based with any clarity to enable the Applicants to respond. *See MPEP § 706* (“The goal of examination is to clearly

articulate any rejection early in the prosecution process so that the applicant has the opportunity to provide evidence of patentability and otherwise reply completely at the earliest opportunity.”)

As a result, if another obviousness rejection is forthcoming, the Applicants respectfully request a more detailed explanation of how Schumacher renders the current application obvious. While the MPEP states that “[i]f the examiner does not produce a prima facie case, the applicant is under no obligation to submit evidence of non-obviousness,” *MPEP* §2142, the Applicants in this case shall make a general argument that these claims are not obvious in light of only Schumacher, as well as arguments that the application is non-obvious in light of both Schumacher and Gordon.

#### B. Schumacher is not Pertinent Prior Art

The first determination that must be made in order to determine obviousness or non-obviousness is the “scope and content of the prior art ... .” *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966).

The analogous-art test requires that the Board show that a reference is either in the field of the applicant's endeavor or is reasonably pertinent to the problem with which the inventor was concerned in order to rely on that reference as a basis for rejection. References are selected as being reasonably pertinent to the problem based on the judgment of a person having ordinary skill in the art. *In re Kahn*, 441 F.3d 977, 987 (Fed Cir., 2006) (citing *In re Oetiker*, 977 F.2d 1443, 1447 (Fed.Cir.1992)).

The claimed invention is not in the same field of endeavor as Schumacher, nor is Schumacher reasonably pertinent to the problem with which the current Applicants seek to solve.

Schumacher's field of endeavor is stated directly in the patent :

##### 1. Field of the Invention

This application pertains to a cleanup kit. More particularly, this application pertains to a kit for cleaning up body substances while abating infection from diseases carried by the substances. *Schumacher col. 1, ll. 8-12.*

In contrast, the current field of invention is:

The present invention relates to medical supplies and means and methods of treating and preparing a medical patient. More specifically the present invention relates to obstetric supplies and obstetric means and methods of treating and preparing an obstetric patient. *Current Specification paragraph 2.*

At least because Schumacher deals with cleaning supplies and the current invention deals with medical supplies, the current application is not in the same field of endeavor as Schumacher.

Also, Schumacher is not reasonably pertinent to the problem being solved by the current application. "A reference is reasonably pertinent if, even though it may be in a different field from that of the inventor's endeavor, it is one which, because of the matter with which it deals, logically would have commended itself to an inventor's attention in considering his problem." *In re ICON Health and Fitness, Inc.*, 496 F.3d 1374, 1380 (Fed. Cir.,2007) (quoting *In re Clay*, 966 F.2d 656, 659 (Fed.Cir.1992)). The claimed invention deals with the long-felt need of "preparing a woman, her partner, and/or caregiver for a miscarriage and for caring for the woman." Schumacher instead discloses an objective of

"provid[ing] a kit for cleaning up human waste in a manner which abates risk of transfer of infectious diseases to the person cleaning the waste. Another object of the present invention is to provide such a cleanup kit which may be *used for a single instance of waste cleanup and readily disposed.*" *Schumacher*, col. 1, ll. 34-40. (*emphasis added*).

A single use kit for cleaning up bodily waste used in a local convenience store or other public place that is then immediately disposed does not "logically commend itself" to the problem of properly preparing and dealing with a miscarriage. A miscarriage is not a once-and-done event such as the problem that *Schumacher* is directed toward. Furthermore, Schumacher does not address the problem of disposal of a fetus (esp. in light of legal requirements for such: *See* MINN. STAT. § 144.1521, 2008 MINN. LAWS CH. 326 HF 3222(4), *Attached as Appendix A* (medical facilities must have in place a policy for informing a woman of available options for fetal disposition when the woman experiences a miscarriage.)), as well as providing a means for determining whether there is an incomplete miscarriage requiring immediate medical attention. One reasonably skilled in the art would not look to Schumacher when trying to solve the problem of caring for a woman going through a miscarriage.

C. Even Considering Schumacher, the Current Application is not Obvious

The Examiner seems to have predicated the obviousness rejection on the Examiner's view that the *Schumacher* invention could *clean up* the final miscarriage remains. *See Office Action dated 9/11/2007 page 3-4, See also Current Office Action page 5.* Even assuming that this is true (which the Applicants assert it is not) this is not the proper question to answer. The question is not whether you can use the prior art to accomplish the same function as the claimed invention in question, but whether "the differences between the subject matter sought to be patented and the prior art are such that the subject matter **as a whole** would have been obvious at the time the invention was made to a person having ordinary skill in the art ..." 35 U.S.C. § 103 (emphasis added). According to the Examiner's viewpoint a new mechanical invention could never be patented so long as another invention in the prior art would be useful for the same function.

The Applicants assert that the objections on obviousness grounds are improper at least because they take too narrow of a view of the current application. "The proper approach to the obviousness issue must start with the claimed invention *as a whole*." *Kimberly-Clark Corp. v. Johnson & Johnson*, 745 F.2d 1437, 1448 (Fed. Cir., 1984) (citing 35 U.S.C. § 103) (emphasis in the original). Furthermore, "[i]t is immaterial to the issue, however, that all of the elements were old in other contexts. What must be found obvious to defeat the patent is the claimed combination." *Id.*

The MPEP provides that "[i]n determining the differences between the prior art and the claims, the question under 35 U.S.C. § 103 is not whether the differences themselves would have been obvious, but whether the claimed invention as a whole would have been obvious." *MPEP* §2141.02 (citing *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 218 USPQ 871 (Fed. Cir. 1983); *Schenck v. Nortron Corp.*, 713 F.2d 782, 218 USPQ 698 (Fed. Cir. 1983)). The Applicants respectfully assert that the invention (in addition to significant deficiencies discussed with respect to the rejections under 120(b)), when viewed as a whole is not obvious from the Schumacher invention as a whole. The primary intent in Schumacher and the problem that Schumacher is trying to solve involves the threat of disease. *Schumacher, col. 1, ll. 19-25.* In contrast, the current invention deals with providing a woman with all reasonably necessary items

before, during, and after a miscarriage. This typically involves not just the one time cleanup of bodily waste, but dealing with sporadic fluid excretions, and the fetal tissue which must be disposed of according to law in a certain way (*See* MINN. STAT. § 144.1521, 2008 MINN. LAWS CH. 326 HF 3222(4), *Attached as Appendix A* (medical facilities must have in place a policy for informing a woman of available options for fetal disposition when the woman experiences a miscarriage.)). The Applicants' invention solves these problems by, for example, providing an "underpad /bed liner", "a specimen pan" and a "container for holding fetal remains for legal disposition," all recited by claim 1. Schumacher discloses none of these and only teaches one time waste cleanup, not multiple use cleanup which also requires human tissue preservation.

Furthermore, contrary to the Examiner's assertions that the Schumacher kit can be used to solve the current problem of miscarriage care, the differences between the *Schumacher* kit and the claimed kit are significant and one of ordinary skill in the art would not know to modify Schumacher to achieve the current application. *See Graham v. John Deere Co.*, 383 U.S. 1, 17 ("differences between the prior art and the claims at issue are to be ascertained;"). While a person having ordinary skill in the art is "a person of ordinary creativity, not an automaton," *KSR Int'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1742, and courts should give credit to such persons to fill in the gaps, the differences between the Schumacher patent and the current application are not mere gaps, but a wide chasm.

It would be a stretch for a person of ordinary skill in the art, given the problems with the Schumacher patent in dealing with the application of Schumacher to a miscarriage to start with or even use Schumacher in dealing with that problem. The modifications to Schumacher necessary to arrive at the current kit that solves the miscarriage problem are significant. The current application discloses an underpad/bed liner, a sanitary napkin, a specimen pan for receiving human tissue and a container for holding fetal remains for legal disposition. None of these elements are present (or suggested, or even hinted at) in Schumacher, either expressly or implicitly. The Applicants submit that the common elements of Schumacher and the present application are extremely minimal(a pair of gloves and a towel). While the Examiner tries to rely on a purported similarity of elements such as a scoop, a cardboard box, or a bottle (pre-filled with sodium hypochlorite) that hypothetically (according to the Examiner) could serve the

purposes of a specimen pan or a container for holding fetal remains, this argument is not only legally insufficient as already explained, these items are incapable of serving these purposes. This is because 1.) the cardboard box and scoop are cardboard or some other necessarily flexible and cheap material as the scoop must be foldable, *See Schumacher column 3 lines 33-61*, and the whole unit in Schumacher is immediately disposable, *See Schumacher col. 1, ll. 37-40*. Such materials are unusable for the purposes of dealing with a miscarriage as many times a miscarriage can last multiple days and using such materials is not sanitary, nor feasible. 2.) None of the items of Schumacher can serve the purpose of holding a fetus for legal disposition. The bottle has a narrow neck that is unsuited for those purposes and would likely not allow for the fetus to be stored in the bottle itself, *See Schumacher Figure 1, item 64*, and the other items again are necessarily made of disposable, flexible materials. The bottle of Schumacher is also sized to hold 6-7 fluid ounces, far below the average sized fetus at 20 weeks gestation. *See Schumacher, col. 3 ll. 15-16, Dean affidavit, page 2* (average sized fetus at 20 weeks is 300 grams – which is 10.5 ounces – the bottle of Schumacher is at least 30% too small to hold an *average* sized fetus at 20 weeks).

Finally, modifying the elements of Schumacher used by the Examiner in making her rejection to cause them to read on the elements would render the Schumacher kit “unsatisfactory for its intended purpose.” The Applicants thus submit that the current invention, as claimed by claims 1,25-31,35-42, is not obvious over Schumacher. *MPEP §2143.01(V)* (“If proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification.” citing *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984)). Specifically, to arrive at the present claims, the towel of Schumacher would need to be a “underpad/ bedliner”, the scoop of Schumacher would need to be a “specimen pan”, and the bottle would need to be a “container for holding fetal remains for legal disposition”.

Modification of a towel to make it a multi-layer absorbent pad that protects the surface it is positioned on renders it unsuitable for use in Schumacher’s waste disposal kit. This is because an underpad/bed liner would increase the size and cost of the kit due to the increased size and thickness of the underpad/bed liner. Further, having a layer that protects a surface up on which it

is placed, or an impermeable layer, makes the liner generally unsuitable for use in a context wherein the liner is merely to wipe up a spill. Indeed, the contrast of such a liner and a paper towel, such as disclosed as a preferable form of towel for the Schumacher kit, illustrates the differences between the discussed elements. *See Schumacher col. 1, ll. 37-40* (“another object of the present invention is to provide such a cleanup kit which may be used for a single instance of waste cleanup and readily disposed.”), *See also Schumacher col. 2, 46-47* (describing the absorbent towels as preferably disposable paper towels).

Modification of the “scoop” of Schumacher to form a “specimen pan,” as claimed would make the Schumacher kit unsatisfactory for its intended purpose. The scoop necessarily has an open side, discussed above. A specimen pan for holding human tissue does not. Were the scoop to be modified to have four closed sides, such as a specimen pan would have, the scoop would be unsuitable for acting as a scoop.

Further, as previously noted, in order to modify the bottle to be able to contain the average fetus size at 20 weeks gestation, the bottle would have to be significantly larger than anticipated by Schumacher in order to accommodate the volume of a fetus that size. As shown in Schumacher’s figures, the bottle has a narrow neck and is not designed to receive a fetus. The narrow neck may be to facilitate pouring of liquid from the bottle (for which the bottle is designed). Increasing the neck size to facilitate receipt of a fetus moves the bottle from its intended purpose. Such modification would render it less suitable as a squirt bottle to dispense disinfectant fluid at the spill, which is what Schumacher uses the bottle for. *Schumacher col. 3, ll. 20-24*.

#### D. Independent Objective Proof of Non-obviousness Ignored.

Once the Patent Office issues a rejection on obviousness grounds, “Office personnel should consider all rebuttal arguments and evidence presented by applicants.” *MPEP §2145*. This includes declarations of non-obviousness by those skilled in the art. *MPEP §2145*, *See also In Re Beattie* 974 F.2d 1309, 1313. The Applicants submitted an expert affidavit from one reasonably skilled in the art describing the invention as “non-obvious” and that the Schumacher kit was not reasonable for use in providing miscarriage support for a woman for two reasons: 1.)



Schumacher is directed toward a one time use only bodily fluid cleanup kit and a miscarriage is a several day event and 2.) nothing disclosed in Schumacher would enable a woman experiencing a miscarriage to dispose of the fetal remains properly. The Examiner dismissed the affidavit for "lack of documentary evidence." The Applicants submit the following references documenting specifically the size of a fetus at 20 weeks: <http://www.babycenter.com/average-fetal-length-weight-chart>. *Attached as Appendix B*. The Applicants further submit that fetus size at a gestational age is a scientific figure and is easy for one skilled in the art to determine. The Examiner did not discuss why the expert affidavit is not valid or convincing with respect to the one time use vs. multiple use issue. The Applicants thus submit that the Examiner inappropriately dismissed the 1.132 affidavit regarding obviousness.

The Applicants thus respectfully assert that the claims are not obvious over Schumacher. Reconsideration and allowance are thus respectfully requested.

**Claim Rejection Under 35 U.S.C. § 103(a)**

Claim 35 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Schumacher (US 4,917,238) in view of Gordon (US 6,434,762). This rejection is traversed at least for the following reasons.

The Examiner begins her rejection by saying:

Schumacher discloses a kit with a specimen pan 80 as disclosed above with respect to claim 1. Schumacher *does not expressly disclose* the pan is configured to fit inside the rim of a toilet. *Current Office Action, page 6*.

The Applicants assume that the Examiner says that such pan is not expressly disclosed as fitting inside the rim of a toilet only to avoid conceding inadequacy of an anticipation rejection. Thus, the Applicants respond to this rejection as if Schumacher does not disclose a pan configured to fit inside the rim of a toilet. The Applicants assume this to be a justifiable position given that the "specimen pan 80" of Schumacher is a collapsible scoop for use in scraping bodily fluids such as vomit off of the floor. *Schumacher, col. 3, ll. 33-61*. If, however, the Examiner actually intends to assert that Schumacher may implicitly disclose that the scoop 80 could fit inside the rim of a toilet, the Applicants would like her to so say so that the Applicants can address that assertion.

In her rejection, the Examiner continues “Gordon discloses a stool/waste collecting apparatus secured to a toilet seat,” and that “[o]ne would be motivated to modify the kit of Schumacher with the specimen pad [sic] of Gordon to improve the anti-contamination of the system since both references disclose apparatus to dispose of bodily waste.”

Gordon discloses:

A stool collecting apparatus is [sic] simple in construction and inexpensive to manufacture and provides an easy to use and contamination free apparatus for collecting a stool sample. The device includes a disposable strip spanning at least a width of a toilet seat having adhesive sections at ends thereof and an opening section between the ends. The opening section includes an opening through the disposable strip and a lip spanning a periphery of the opening. A sealable stool receptacle is removably secured to the lip adjacent the opening section. After a sample is deposited, the receptacle can be easily removed from the disposable strip and sealed for subsequent processing. The strip, with or without a seat cover, can then be discarded. *Gordon, Abstract.*

Modification of the Schumacher scoop to collect feces in this way would render it inoperable for its intended purpose as a scoop and thus modification of the Schumacher scoop in this way does not render the current claims obvious. *MPEP §2143.01(V)* (“If proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification.” citing *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984)). Modification of the scoop to collect feces as it exits the patient would require a completely enclosed container to prevent the feces (which may be diarrhea) from spilling out the open end and to enable the secure collection of the feces, and to ensure that outside environmental contamination of the sample does not occur.

The patient can deposit a stool sample in the stool receptacle without fear of touching the sample, and the sealed receptacle is free from human and/or foreign contamination (whether from the patient’s hands, urine leakage, toilet bowl water, possible pollutants ... See *Gordon*, column 3, ll. 33-39

However, this is inconsistent with the definition of the scoop in Schumacher which has an open end to receive the bodily fluids that are “scooped” into the scoop with the scraper. See *Schumacher*, 80, 90. If the scoop were enclosed on all sides, it could not serve its intended

purpose to be a receptacle to receive the waste that is scraped into the scoop. *Schumacher*, col. 4, l. 26.

Further, the collecting apparatus of Gordon does not comprise a “specimen pan having an opening positioned and sized to receive fluids and human tissue from a miscarriage,” as recited by claim 35. One difference between the collecting apparatus of Gordon and the specimen pan of present application are the respective locations for positioning on the toilet seat. For Gordon, it is positioned to “collect a stool sample.” *Gordon*, col. 1, l. 36, and thus must be positioned below the user’s anus. For the present application, the location of the collection device must be below the vaginal area to collect the human tissue or fetal remains. *See Claim 35*. Gordon specifically cautions against collection of urine as it might contaminate the sample. *See Gordon*, column 3, ll. 33-39. Placement of Gordon below the vagina would inevitably render Gordon unusable as it would contaminate the stool sample collected by Gordon.

The Applicants further assert that Gordon fails to correct the other fundamental teaching deficiencies of Schumacher, discussed above.

Again, the Applicants re-iterate that “[i]n determining the differences between the prior art and the claims, the question under 35 U.S.C. 103 is not whether the differences themselves would have been obvious, but whether the claimed invention as a whole would have been obvious.” *MPEP* §2141.02 (citing *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 218 USPQ 871 (Fed. Cir. 1983); *Schenck v. Nortron Corp.*, 713 F.2d 782, 218 USPQ 698 (Fed. Cir. 1983)). The Applicants assert that it would not be obvious to combine a waste *cleanup* kit to a stool *collection* kit to create a miscarriage *care* kit.

Schumacher and Gordon, alone or in combination, do not make obvious the specimen pan of the current invention that is

configured to fit inside the rim of a toilet and further includes an upper rim configured to allow the upper rim to rest atop the toilet rim, the specimen pan having an opening positioned and sized to receive fluids and human tissue from a miscarriage, and wherein the specimen pan is comprised of a durable material; and wherein the specimen pan provides a measurement guide for measurement of fluid loss ... *Claim 35*.

Claim 35 is thus allowable over Schumacher, and over Schumacher in light of Gordon.  
Reconsideration and allowance are thus respectfully submitted.

**CONCLUSION**

In light of the above, it is respectfully submitted that the present application is in condition for allowance. Reconsideration of the present application and a favorable response are respectfully requested. If the Examiner feels an interview would facilitate prosecution of the present application, the Applicants' representative is available for such interview.

This response is being submitted on or before June 17<sup>th</sup> 2008 making this a timely response. It is believed that no additional fees are due in connection with this filing. However, the Commissioner is authorized to charge any additional fees, including extension fees or other relief which may be required, or credit any overpayment and notify us of same, to Deposit Account No. 04-1420.

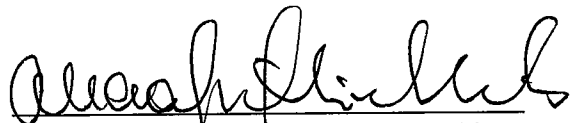
Respectfully submitted,

DORSEY & WHITNEY LLP  
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Date: \_\_\_\_\_

June 17, 2008

By: \_\_\_\_\_

  
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